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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,007	10/10/2002	Colin Wesley Ward	7-02	5750

23713 7590 03/29/2004

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SUITE 201
BOULDER, CO 80303

EXAMINER	
ANDRES, JANET L	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,007	WARD ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-57* is/are pending in the application.

4a) Of the above claim(s) *45-47,52 and 55-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-44,48-51,53 and 54* is/are rejected.

7)☒ Claim(s) *50 and 51* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 October 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2 October 2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the response filed 9 January 2004 is acknowledged. The traversal is on the ground(s) that the claims were improperly restricted under 35 U.S.C. §121. Applicant argues that the claims should properly have been restricted under unity of invention practice. While Applicant is correct that the claims should have been restricted under PCT rules, the restriction itself is proper because truncated EGF receptors are known in the art (see below) and thus there is no special technical feature linking the inventions.

The requirement is still deemed proper and is therefore made FINAL. Claims 23-57 are pending in this application. Claims 45-47, 52, and 55-57 are withdrawn from consideration as being drawn to a non-elected invention.

Specification

2. The abstract of the disclosure is objected to because there appears to be a typographical error. It is believed that Applicant intended to specify TGF-α, not "TNFI". Correction is required. See MPEP § 608.01(b).

Claim Objections

3. Claims 50 and 51 are objected to because of the following informalities: They contain a typographical error; see the third word of each. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 23-34 and 41-44 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Reiter et al. (Nucleic Acids Res. 1996, vol. 24(20), pp. 4050-4056).

Reiter et al. teaches a truncated human EGFR, ErbB1-S, that contains the first two domains and part of the third (p. 4055, column 1 and figure 5A). The ligand binding properties are not disclosed but are an inherent feature of the protein.

6. Claims 23-36 and 41-44 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Maihle et al. (Proc. Nat. Acad. Sci. 1991, vol.88, pp. 1825-1829).

Maihle et al. teaches a truncated avian c-ErbB that contains all of the first three domains and the first two amino acids of the fourth. See p. 1828, figure 7. As stated above, the ligand binding properties are inherent to the protein.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 48-51 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiter et al. or Maihle et al. in view of Ashkenazi et al. (Current Opinion in Immunology 1997, vol. 9, pp. 195-200).

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Reiter et al and Maihle et al. teach as set forth above and further teach that the soluble EGFR forms are of interest in cancer (Reiter et al., p. 4050, column 1) or may have other physiological roles (Maihle et al., p. 1825, column 2). Neither Reiter et al. nor Maihle et al. teaches fusion proteins. Ashkenazi et al. teaches that Fc fusions are useful to investigate molecular interactions (p. 196, column 2) and for treatment of disease (p. 197). It would be obvious to one of ordinary skill in the art to combine the teachings of Reiter et al or Maihle et al. with those of Ashkenazi et al. to prepare fusion proteins of soluble EGR and Fc. One of ordinary skill would be motivated to do so because Reiter et al. and Maihle et al. teach areas of research and of interest in disease for the proteins and Ashkenazi et al. teaches useful tools for research and therapy.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 23-44, 48-51, 53, and 54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the 1-501 truncation of human EGFR, does

not reasonably provide enablement for all truncations of all EGFR and EGFR-like proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman,* (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands,* 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Since there is no lower size limit in claims 23-34, 41-44, 48-51, 53, and 54, and all of the claims use "comprising" language, the claims encompass all versions of EGFR shorter than the ectodomain. Since Applicant's definition of "EGFR" encompasses all members of the EGF receptor family, the claims also encompass truncations of several different molecules, as well as undescribed molecules that might fall into the category of "EGFR". They further encompass proteins made by all species of animals. Applicant has described one truncation, the 1-501 truncation of human EGF receptor that exhibits the desired property. However, applicant has not described the characteristics of this truncation so that one of skill in the art could predictably identify other truncations with the same enhanced affinity. Applicant has not described the properties or characteristics that are required for the enhanced activity. Thus, the essential characteristics of EGFR truncations are not described. Further, while recombinant techniques are available, it is not routine in the art to screen large numbers of nucleic acids that might potentially encode such proteins where the expectation of obtaining similar activity is

unpredictable. Thus one of skill in the art would require additional guidance, such as information as to what structural features are necessary for the enhanced binding, in order to practice the invention commensurate with the scope of the claims without undue experimentation.

11. Claims 23-44, 48-51, 53, and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has described one truncated EGF receptor. However, the claims encompass all versions of EGFR shorter than the ectodomain as well as all molecules that might fall into the category of "EGFR" and all species that express such molecules. The instant disclosure of one protein thus does not adequately describe the scope of the claimed genus. There is no description of the required structural and functional features of the claimed molecules, or of the regions that would be critical for these features. Since these features are not disclosed, there is no way to determine what truncations would possess the same defining characteristics. Further, the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify EGFR with enhanced binding affinity Therefore, applicant has not disclosed sufficient species or common structural features such that one skilled in the art would conclude that applicant was in possession of the claimed genus of all EGFR truncations with enhanced affinity.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 23-44, 48-51, 53, and 54 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are drawn to EGFR truncations. However, EGFRs are not defined on p. 6 so that one of skill in the art would be able to determine what molecules were encompassed. The definition on p. 6 (lines 21-24) includes all molecules that might be described as member of the EGF receptor family, with no defining characteristics of the family.

These claims are also indefinite because they claim particular regions, identified by name or by amino acid range, of molecules that are not themselves defined. No reference is made to sequences, so that the skilled artisan could, for example, identify residue 502 in another family member or another species of animal. The different regions are similarly not described so that the skilled artisan would be able to identify, for example, "L1" of another member of the family.

The claims are additionally indefinite because claim 23 requires that a "substantial portion" be lacking. The size of the portion that would be considered "substantial" is not defined and one of skill in the art would not know how much of the molecule was required to be missing.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
25 March 2004